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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,284	02/07/2005	Gesine Schliecker	I-2002.001 US	5686

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Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/501,284	SCHLIECKER ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/09 has been entered.

Previous Claims and Rejections Status

2. Claims 1-19 and 21-26 are pending in the application. Claims 22-26 were newly added in the amendment filed 6/9/09.

3. The rejection of claims 1-19 and 21 under 35 U.S.C. 103(a) as being unpatentable over Krone et al. (US 5,391,696) in view of Suzuki et al. (US 6,015,789) and in further view Ishino et al. (*Chem. Pharm. Bull.* **1992**, *40*, 3036-3041) and Maggi et al. (*Biomaterials* **2002**, *23*, 1113-1119) is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1,3-6,8,9,13,22 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Krone et al. (US 5,391,696) as evidenced by Lewis (US 5,838,571).

6. Krone et al. (US 5,391,696) teaches of formulations comprising polytartrate polymer; polyethylene glycol; therapeutic agents; pharmaceutically acceptable excipients, etc. (abstract; column 10, lines 36-45 and 54-59). The formulation may comprise tablets formed via compaction/compression which do not comprise a barrier structure (column 11, lines 35-40). Standard tablet compression force of a conventional tablet is defined by Lewis as being in the range of 18 to 27 kN (column 13, lines 1-7). The formulation of Krone et al. anticipates the composition of the instant claims and is capable of the same functions, such as forming degradation products that increase the pressure inside the composition, capable of releasing the pharmaceutically active material in a pulsatile or triphasic manner, etc. and has the same properties, such as a glass transition temperature that is greater than 40°C.

7. It is respectfully pointed out that instant claims 1,3-6,8,9,13,22 and 24-26 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113. The tablet preparation prepared via compression force of the

instant claims is anticipated by Krone et al. (as evidenced by Lewis) and therefore the burden is shifted to applicant to show that the pharmaceutical composition of the instant claims is materially different than the polytartrate polymer formulation of Krone et al.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krone et al. (US 5,391,696) in view of Lewis (US 5,838,571) and in further view of Suzuki et al. (US 6,015,789) and Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89.

10. Krone et al. (US 5,391,696) discloses formulations comprising polytartrate polymer, such as (2',3'-(1',4'-diethyl)-L-tartyl poly-(2,3-O-isopropylidene)-L-tartrate); buserelin; polyethylene glycol and pharmaceutically acceptable excipients, etc. (abstract; column 10, lines 36-45 and 54-59). The formulations of the disclosure may comprise tablets formed via compaction/compression which do not comprise a barrier structure (column 11, lines 35-40). Krone et al. teaches that preparations have a decreased "initial burst" (column 2, lines 21-25).

11. Krone et al. does not disclose the method of administering the pharmaceutical composition, the GnRH agonist nafarelin or method of preparing a polytartrate tablet.

12. Lewis (US 5,838,571) teaches that standard tablet compression force of a conventional tablet is in the range of 18 to 27 kN (column 13, lines 1-7).

13. Suzuki et al. (US 6,015,789) discloses a pharmaceutical composition/solid tablet preparation comprising a GnRH agonist, such as buserelin or nafarelin, pharmacologically acceptable carrier, etc. for administration to a human being (claims 1,2; column 97, lines 63-66; claim 2; column 98, lines 17-25; column 101; column 102, lines 45-55). The pharmaceutical composition/solid tablet preparation comprising excipients (i.e. polyethylene glycol) which are prepared via compression (column 99, lines 23-33).

14. Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89 discloses the preparation of oral solid dosage forms from granulation techniques which involve mixing the materials, sieving the mixture and shaping the mixture with tabletting equipment (especially see p1634; methods of preparation p1641-1646).

15. It is respectfully pointed out that instant claims 1-19 and 21-26 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

16. At the time of the invention it would have been obvious to one ordinarily skilled in the art to include the buserelin or nafarelin of Suzuki et al. in the polytartrate solid tablets (prepared via compression) of Krone et al. as both disclosures are drawn to solid tablet preparations comprising buserelin. One skilled in the art would have a reasonable expectation of success for substituting one equivalent GnRH agonist for another, such as buserelin for nafarelin. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. Suzuki et al. teaches of the administration of nafarelin/buserelin preparations to a human and therefore it would have been obvious to one skilled in the art to administer a polytartrate composition comprising nafarelin/buserelin to a human.

17. The standard compression force for the preparation of a conventional tablet is in the range of 18 to 27 kN and therefore the polytartrate solid tablets (prepared via compression), which do not comprise a barrier structure, of Krone et al. encompass the composition of the instant claims which is prepared via compression with a compression force from 10 to 65 kN/cm^2. Krone et al. does not explicitly teach that the tablets are pulsatile but teaches that the polytartrate composition (prepared via compression) have a decreased "initial burst" which shows that they provide an initial burst and thus are pulsatile to a degree.

18. Remington's pharmaceutical sciences teaches of standard oral tablet formation involves mixing the components of the composition, sieving and compressing with

tabletting equipment and therefore it would have been obvious to one skilled in the art to use these standard techniques for the preparation of the polytartrate composition of Krone et al.

19. The formulation of Krone et al. encompasses the composition of the instant claims and is capable of the same functions, such as forming degradation products that increase the pressure inside the composition, capable of releasing the pharmaceutically active material in a pulsatile or triphasic manner, etc. and has the same properties, such as a glass transition temperature that is greater than 40°C. Therefore the burden is shifted to applicant to show that the pharmaceutical composition of the instant claims is materially different than the polytartrate polymer formulation of Krone et al.

Response to Arguments

20. Applicant's arguments filed 6/9/09 have been fully considered but they are not persuasive.

21. Applicant asserts that the references fail to teach or suggest that the pharmaceutical composition "does not comprise a barrier structure" as recited by amended claims 1 and 14. Applicant also asserts that Ishino is the only reference that teaches pulsatile release of a pharmaceutically active material but accomplishes that the pulsatile release through the use of a PEG barrier structure or that the majority of the pharmaceutically active material is released in an initial burst and a second burst.

22. The assertions with regards to Ishino are moot as the reference has been withdrawn.

23. Krone et al. teaches of polytartrate, pharmaceutically active material, etc. tablets which do not comprise a barrier structure and are prepared via compression. Standard tablet compression force of a conventional tablet is defined by Lewis as being in the range of 18 to 27 kN (column 13, lines 1-7). The preparations of Krone et al. have a decreased "initial burst" which shows that they are pulsatile and do have an initial burst, albeit reduced. The implication of the recitation of an "initial burst" is that there are subsequent bursts. Therefore the tablet preparation via compression force of the instant claims is anticipated by Krone et al. (as evidenced by Lewis) and therefore the burden is shifted to applicant to show that the pharmaceutical composition of the instant claims is materially different than the polytartrate polymer formulation of Krone et al.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618